

### **REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

By way of this amendment, claims 1 and 11 have been amended and claim 10 has been canceled. In claim 1, the term “passively” has been deleted and the term “specifying” has been replaced with the term “detecting.” Claim 11 has been amended to recite a method for screening a substance affecting the action of a trigger protein on the indicator substance detected in claim 1, comprising contacting the trigger protein with the indicator substance in the presence or absence of the candidate substance, and comparing changes in the indicator substance. Full support for the amendments can be found throughout the present application and the claims as originally filed. For example, support for the amendments can be found at least in paragraphs [0017]-[0019] and [0057] of the present application. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

#### **Restriction Requirement**

At page 2 of the Office Action, the Examiner states that the restriction requirement of record, mailed June 26, 2008, is withdrawn because the applicants' arguments in the reply filed on July 14, 2008, were found persuasive. The applicants appreciate the Examiner's removal of the restriction requirement.

#### **Specification**

At page 3 of the Office Action, the Examiner states that the specification should be amended to reflect proper use of trademarks and the proper language and format for an “Abstract” of the

disclosure.

The references to trademarks in the specification have been corrected, as suggested by the Examiner. The "Abstract" has also been amended to better comply with the requirements of the M.P.E.P.

Accordingly, this objection should be withdrawn.

**Arrangement of the Specification**

At page 4 of the Office Action, the Examiner states that the "Brief Description of the Drawings" should appear immediately after the "Brief Summary."

The specification has been amended to include the "Brief Description of the Drawings" immediately after the "Brief Summary."

Accordingly, this objection should be withdrawn.

**Rejection of claims 1-19 under 35 U.S.C. §112, second paragraph**

At page 5 of the Office Action, the Examiner rejects claims 1-19 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the term "passively" in claims 1 and 10 is a relative term which renders the claim indefinite. The Examiner also states that in claim 1, it is not clear what is meant by "specifying the substance change." This rejection is respectfully traversed.

In claim 1, the term "passively" has been deleted and the term "specifying" has been replaced with the term "detecting." Claim 10 has been canceled.

Accordingly, this rejection should be withdrawn.

**Rejection of claim 10 under 35 U.S.C. §101**

At pages 5-6 of the Office Action, the Examiner rejects claim 10 under 35 U.S.C. §101 because the claimed invention is directed to non-statutory matter. The Examiner states that claim 10 does not sufficiently distinguish over the claimed biomarker as it exists naturally. The Examiner suggests inserting the term “isolated” or “purified” in the claim to further define the claimed protein. This rejection is respectfully traversed.

Claim 10 has been canceled, rendering this rejection moot.

Accordingly, this rejection should be withdrawn.

**Rejection of claims 1-8 and 10-19 under 35 U.S.C. §103(a)**

At pages 6-7 of the Office Action, the Examiner rejects claims 1-8 and 10-19 under U.S.C. §103(a) as being obvious over Sawasaki et al. (PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, USA Vol. 99, No. 23, November 12, 2002, pages 14652-14657) in view of Kato et al. (U.S. Patent No. 6,268,157). The Examiner states that Sawasaki et al. teaches a cell-free protein synthesis system based on the eukaryotic translation apparatus of wheat seeds and allows for the screening and synthesis of gene products. The Examiner states that Sawasaki et al. differs from the instant invention in not specifically teaching the inclusion of an indicator substance. The Examiner states that Kato et al. describes screening methods that can specifically identify inhibitors and accelerators for use in disease treatments. The Examiner states that it would have been obvious to one of ordinary skill in the art to utilize the screening assay of Sawasaki et al. to measure indicator substances because Kato et al. describes screening methods that identify inhibitors and accelerators for use in disease treatments. This rejection is respectfully traversed.

Sawasaki et al. describes a cell-free system for synthesis and screening of gene products. Thus, Sawasaki et al., like conventional screening methods, identifies only the products or end products of protein synthesis. Unlike Sawasaki et al., the claimed invention provides a method for screening intermediates and complex proteins produced in a series of intracellular phosphorylation steps in intracellular signaling systems. Further, as acknowledged by the Examiner, Sawasaki et al. does not describe an indicator substance. In particular, the present claims provide, in part, contacting a trigger protein prepared by a cell-free protein synthesizing means with a target cell extract which contains an indicator substance that is produced by an action induced by the trigger protein. Sawasaki et al. does not describe an indicator substance that is produced by an action induced by the trigger protein. Contrary to the Examiner's assertion, however, Kato et al. does not overcome this deficiency. Kato et al. describes screening for a substance that inhibits or induces interaction between an intranuclear receptor and a Smad molecule. Kato et al. does not describe an indicator substance that is produced by an action induced by a trigger protein. As such, the combination of Sawasaki et al. and Kato et al. would not lead one of ordinary skill in the art to arrive at the present claims.

Accordingly, this rejection should be withdrawn.

**Rejection of claim 9 under 35 U.S.C. §103(a)**

At pages 8-9 of the Office Action, the Examiner rejects claim 9 under U.S.C. §103(a) as being obvious over Sawasaki et al. (PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, USA Vol. 99, No. 23, November 12, 2002, pages 14652-14657) in view of Kato et al. (U.S. Patent No. 6,268,157), and further in view of Foster et al. (U.S. Patent No. 4,444,879). The Examiner states that Sawasaki et al. in view of Kato et al. differ from the instant invention in not

specifically teaching kit configurations. The Examiner states that Foster et al. describes kits for assay reagents. The Examiner believes that it would have been obvious to one of ordinary skill in the art to arrive at present claim 9 given the teachings of Sawasaki et al., in view of Kato et al., and further in view of Foster et al. This rejection should be withdrawn.

For the reasons provided above, neither Sawasaki et al. nor Kato et al. teach or suggest a method for screening an indicator substance produced by an action induced by a trigger protein, as recited in the present claims. Foster et al. does not overcome the deficiencies identified above in Sawasaki et al. and Kato et al. Foster et al. relates to a solid-phase support for immobilizing reactants of an immunoreaction. Foster et al. does not teach or suggest a method for screening an indicator substance produced by an action induced by a trigger protein, as recited in the present claims. As such, the cited references do not, alone or in combination, teach or suggest the present claims.

Accordingly, this rejection should be withdrawn.

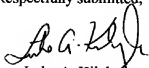
## **CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

U.S. Patent Application No. 10/575,807  
Amendment dated December 22, 2008  
Reply to Office Action of September 30, 2008

Respectfully submitted,



Luke A. Kilyk  
Reg. No. 33,251

Atty. Docket No. 3190-096  
KILYK & BOWERSOX, P.L.L.C.  
400 Holiday Court, Suite 102  
Warrenton, VA 20186  
Tel.: (540) 428-1701  
Fax: (540) 428-1720